

TOBACCO

Q: Why regulate tobacco?

A: Nicotine addiction is a pediatric disease. Every day, almost 3,000 young people become regular smokers; nearly 1,000 of them will ultimately die younger due to cancer, emphysema, heart disease and other diseases caused by smoking. Smoking kills more than 400,000 Americans per year -- more than AIDS, alcohol, car accidents, murders, suicides, illegal drugs and fires combined. More than 80% of adult smokers start smoking before their 18th birthdays. In fact, smokers almost always become addicted during their teenage years. And youth smoking is on the rise. In 1995, more than a third of high school seniors smoked cigarettes -- more than at any time since the 70s -- and close to 28% of tenth graders smoked as well.

Q: What is being announced Friday?

A: Friday, you will announce the culmination of over two and a half years' work by the FDA to complete a final rule to combat children's smoking. First, FDA investigated and studied for 18 months to develop a proposed rule. In August, 1995, you announced the promulgation of that proposed rule to curb access and appeal of tobacco to young people. Over the last year, the FDA reviewed comments, including more than 95,000 different comments totalling more than 700,000 pieces of mail, and considered various changes to the original proposal. FDA revised the rule in response to public comments and in an effort to make it more closely targeted to kids. Then OMB reviewed the rule for compliance with your priorities and various regulatory policies. Upon OMB's sign-off, the rule will be placed on display at the Federal Register on Friday and will be published next week.

Q: What does the final rule do?

The FDA rule reduces children's easy access to tobacco products by: requiring age verification by photo ID for anyone under 26 for anyone purchasing tobacco products; banning vending machines and self-service displays except in "adult" facilities where children are absolutely not allowed, such as certain nightclubs; banning free samples; banning the sale of single cigarettes and "kiddie packs" -- packs with fewer than 20 cigarettes.

The FDA rule limits the appeal of tobacco products to children by:

Prohibiting billboards within 1000 feet of schools and playgrounds. Other advertising is restricted to black-and-white text only; this includes all billboards, signs inside and outside of buses, and all ads in stores or at other points of sale. Ads inside "adult only" facilities like nightclubs are unrestricted if they cannot be seen from outside and are not removable.

Permitting only black-and-white text ads in publications with 15% or more, or 2 million or more, readers under 18. No restrictions on ads in other magazines.

Banning sale or giveaways of products like caps or gymbags that carry cigarette or smokeless tobacco product brand names or logos.

Banning brand-name sponsorship of sporting or entertainment events but permitting it in the corporate name.

Q: When does this rule go into effect?

A: The provisions will be phased in between six months and two years from the date of publication in the Federal Register in order to give businesses time to comply.

Q: What are the differences between the proposed rule and the final rule?

A: In reviewing the more than 95,000 different comments received from the public, the FDA made a number of changes aimed at more narrowly targeting the rule to the goal of reducing the use of tobacco by kids. Changes include:

Allowing vending machines and self-service displays and unrestricted advertising in facilities where only adults are permitted. By removing vending machines from places where kids can get to them, the rule's goal will be achieved without hindering adults in adult-only settings like certain nightclubs.

Mail orders will be permitted because there was little evidence presented that children use mail order at the present time, yet some adults in rural or isolated areas rely on mail order to have access to cigarettes.

Q: Didn't the proposal also have a requirement that the industry fund an education campaign and didn't you remove it from the final rule?

A: A different provision of FDA's statute, section 518(a), provides explicit authority to the FDA to require device manufacturers, which now include tobacco manufacturers, to notify people about a risk presented by use or misuse of their devices, when notification is needed to eliminate an unreasonable risk of harm. The FDA decided this is a more appropriate provision for it to use to achieve the goals of the educational campaign. Therefore, in addition to the rule that is going on display on Friday, the FDA also will propose to require tobacco companies to provide strong messages for children on the real dangers of smoking and using smokeless tobacco. This national media campaign could include television spots. The companies will be given an opportunity to consult with FDA about the necessity and form of the education campaign before the FDA issues any directives.

Q: What are the health benefits of the rule?

A: Health care costs associated with smoking are rising. The CDC estimated that in 1993, the health care costs associated with smoking totalled \$50 billion: \$26.9 billion for hospital costs; \$15.5 billion for doctors; \$4.9 billion in nursing home costs; \$1.8 billion for prescription drugs; and \$900 million in home health care expenditures.

Q: In taking this action are you or the FDA declaring tobacco to be a drug?

A: FDA's regulation is based on its conclusion that cigarettes and smokeless tobacco are drug delivery devices for the highly addictive drug nicotine.

Q: Is the FDA saying the tobacco companies are trying to addict people?

A: FDA found that nicotine is addictive, and that manufacturers legally intend this effect because they design these products to provide a pharmacologically active dose of nicotine and an clear consequence is to sustain consumers' addiction to nicotine.

Q: Is the FDA saying that the tobacco companies intentionally target children?

A: The FDA did not go into the question of whether the companies intentionally target children. They did, however, find significant evidence that advertising plays an important role in young people's decisions to use tobacco. For example, almost 90% of young smokers choose the three most heavily advertised brands.

Q: Isn't this censorship in violation of the First Amendment?

A: The Department of Justice is confident that this rule is consistent with recent Supreme Court rulings. The sale of tobacco to children is illegal, so if the advertising is related to illegal sales to children, it is constitutional to limit it. Plus, the FDA put the rule together so it is very narrowly tailored to get just at kids smoking -- that's why vending machines are only banned in places kids can get to, but not in places like certain bars where you can't get in without an ID card that says you're 18.

Q: If tobacco is so bad for people, why not just ban it altogether?

A: A prevention strategy aimed at kids is the most effective approach. The regulation will reduce the tobacco available to kids, while allowing it to be available to adults users, who typically are already addicted. We have learned from the alcohol prohibition experience, that a ban will not eliminate the tobacco use of addicted adults; it will lead to a black market, with perhaps even higher health risks for people.

Q: Now that the rule is out, will you support legislation?

A: For over a year, I've said that I'd support legislation as comprehensive as the FDA's proposals -- it would be better than the prospect of a lot of litigation. I still believe that and would welcome Congressional action to enact what we've been able to do through executive action with the FDA rule.

Q: What is the impact on tobacco growers?

A: The effect on tobacco farmers is expected to be extremely gradual, at most a 4% change in tobacco sales in 10 years. Tobacco will remain a legal crop and millions of adults will continue to use these products. Many tobacco farmers are looking at diversifying and several states have programs aimed at helping them do this. We can all surely agree that no one wants to make money from smoking by our kids.

Q: The FDA has been criticized for being slow on getting new drugs on the market. Will this new initiative take away even more of its resources and make the drug approval process slower?

A: FDA is actually a world leader in both the speed and quality of drug approvals. Much of the regulation, such as review of tobacco advertising, can be done with current agency resources. There may be some small resource needs, but they are justified by the fact that every year another million young people become regular smokers, and a third of them will die because of it.

Q: How will the FDA enforce these regulations?

A: The regulations set some bright line standards. These provisions are virtually self-enforcing because it is clear where vending machines are allowed and where billboards are prohibited. We will work in partnership with states and localities. And, a violation of these rules is a violation of the Food Drug and Cosmetic Act and will be enforced accordingly.

Q: Did the White House have a lot of changes to the FDA's proposed draft final rule?

A: No. There were a handful of technical changes suggested by the regulatory review staff at OMB. But basically, Dr. Kessler and the FDA are the experts and spent over a year reading and responding to comments, and making changes to tighten the rule and make it more targeted to kids, and I think they hit it right on.

Q: How could the rule be finished so fast...did you rush it because of the Convention coming up?

A: There was nothing fast about it. The FDA took 18 months to develop the proposed rule that I announced a year ago, based on intense investigation and study. Then they took another year to read through the 95,000 different comments totaling more than 700,000 pieces of mail, and to respond to those comments and make changes based on them. And, as you can see, they gave those comments serious attention and tightened up the rule to make it more targeted to kids. With 3000 young people taking up smoking every day, it was important that the FDA make this a high priority -- but they certainly gave the rule thorough consideration.

Q: Will anything really happen here? Aren't you going to be tied up in lawsuits for years?

A: Well, that depends on the tobacco industry. And they've filed the suits last year. But I would hope they might come around and we have reason to believe they will since they have acknowledged the problem. This is all about our kids and their futures, and whether another million kids each year are going to become hooked and a third of them will have their lives shortened.

Q: You announced this rule on the eve of this Convention...and various receptions at your Convention will be underwritten by tobacco companies? How is that consistent with your policies?

A: The real question is who is doing the right thing when it comes to our kids. My administration was the first to seriously take on the issue of children smoking. Every day nearly 3,000 of our young people start smoking and that will shorten the lives of almost 1,000 of them. Everyone from parents to teachers to community leaders to the federal government needs to do their part to end this tragedy. What I've been critical of is the apparent impact the tobacco industry's contributions have had on the Republican's policy decisions. We have had real opposition by Senator Dole to this initiative. The Washington Post reported recently that 85% of tobacco industry money has gone to the Republicans. You can judge for yourself whether contributions have had anything to do with our opposing policy positions.

Q: How does your trade policy mesh with this tobacco rule?

A: My administration changed the trade policy process so that HHS is now involved in cigarette trade policy discussions. And, because of that, we have a policy where if another country wants to enact legitimate health measures to protect its citizens -- like measures to keep tobacco away from kids -- we respect that. In fact, we applaud other nations' efforts and we are working with them to address kids' smoking and would support stronger efforts around the world to protect kids from tobacco addiction.

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So, while in general, our policy is to insist that U.S. products not be discriminated against, my administration is the first to say this should not undermine other countries legitimate health policies.

Q. What is the relationship between smoking and illicit drug use?

A. Studies show that underage smokers are more likely than non-smokers to use illicit drugs, although most young smokers do not use illegal substances. A causal link between smoking and illicit drug use has not been established.

We are very concerned too many young Americans are engaged in a whole range of risky behaviors, including the use of tobacco and illicit drugs. We have powerful, comprehensive strategies for preventing each of these behaviors.

Q. But a lot of people are calling tobacco a "gateway drug." They're citing studies that say if you've smoked cigarettes as a child, you're much more likely to develop an addictive problem later in life. Do you believe that tobacco use by children is a gateway to illicit drugs?

A. Scientific evidence has not established that tobacco is a gateway drug. We do know that a significant portion of young people who use tobacco also use illicit drugs. That's why we're working aggressively to educate youth about why they should not use tobacco or illicit drugs.

Q. Why is the Administration focusing on nicotine when illegal drug use is causing more serious problems in this country?

A. This Administration has been fighting hard against illegal drug use. At the same time, we cannot ignore the fact that smoking is the leading cause of preventable death in this country, that 3000 children become regular smokers each day, and that 1000 lives will be shortened as a result. We must focus on both. This is not an either/or situation.

Q: Earlier this week your Administration announced that illegal drug use among teens is rising. Is this initiative the Administration's answer to rising drug use among teenagers? Is this announcement politically timed to deflect criticism about rising illegal drug use?

A: No. The reason for this initiative is the public health tragedy of children's tobacco use. The Administration proposed the tobacco rule a year ago. The final rule just completed the OMB review process and is ready, so we are announcing it today. Remember, 3,000 young people a day become regular smokers. We can't afford to waste even one day in addressing this tragedy.

But make no mistake, we are deeply concerned about the rise in youth drug use. That's why the top priority of the National Drug Control Strategy is to reduce drug

and substance abuse among youth. Over the last four years the we have expanded youth drug prevention programs and fought Republican efforts to gut these programs. In the 1996 State of the Union address, I challenged parents to talk openly and firmly to their children about the harm of drugs. Our drug control strategy is comprehensive: we're working with parents, schools, communities, religious organizations, businesses, the media and entertainment industries, state and local government, and young people themselves to make sure that America's youth hear a powerful and consistent anti-drug message.



White House Press Release

Radio Address Of The President To The Nation

The White House

Office of the Press Secretary

Embargoed For Release
Until 10:06 A.M. Est
Saturday, November 9, 1996

Radio Address Of The President
To The Nation

The Oval Office

The President: Good morning. Today I want to talk with you about what we can do as a nation to help parents as they try to raise their children. This week the American people came together to say that we are on the right track to the 21st century. They said we must continue to make real our vision to create an America where we offer opportunity to all; demand responsibility from all, and build a stronger American community of all Americans where everyone has a role to play.

At the heart of this mission has been our effort to strengthen America's families. This is work I am determined to build upon these next four years. We will continue to strengthen families by creating economic opportunity, so that hard-working parents can provide for their children. To do that, I asked Congress to join with me to finish the job of finally balancing the budget in a way that protects our values.

We will continue to strengthen families by helping parents to succeed at work and at home; by giving families safe streets to walk on and communities free from gangs and guns and drugs; and by expanding educational opportunity so that literacy is a given and college is within reach of all Americans.

We will continue to strengthen families by helping parents to protect their children from bad influences that come from outside the home. American parents are working overtime to set good examples, only to have the full force of popular culture make their work harder. That's why we gave parents the v-chip and a television system so they can keep televised violence and explicit sexuality out

system so they can keep televised violence and explicit sexuality out of their young children's lives. And that's why we'll continue our efforts to help parents protect their children from the corrosive dangerous influences of tobacco and **alcohol**.

We know the plower of tobacco advertising to reach out to children every day and to get them hooked on a habit we know is deadly. Every day nearly 3,000 young people start to smoke in this country, even though it's illegal to sell cigarettes to them. This week we received further chilling evidence why we must remain vigilant in our efforts to protect our children from tobacco.

According to a report released by the Centers for Disease Control and Prevention, more than 5 million Americans under the age of 18 who smoke today will eventually die prematurely from smoking. The Cdc estimates that today's teen smokers will run up an estimated \$200 billion in projected health care costs from tobacco-related illnesses. Their premature deaths will cut approximately 64 million years off the lives of Americans.

That's why my administration has taken tough, unprecedented action to stop advertising and marketing of cigarettes that can persuade teenagers to smoke. We're banning tobacco

advertising on billboards near schools, ending cartoon characters in ads that children will likely see, restricting the cigarette machines that make it easier for children to illegally buy cigarettes.

The Cdc report shows that when parents, teachers, doctors, and government work together we can stop people from smoking. The Cdc studied two states that have put in place strong anti-smoking initiatives, California and Massachusetts. Both now have smoking rates lower than the national average, and both have seen smoking drop dramatically -- 15 percent in California, and 20 percent in Massachusetts.

These reports tell all of us, keep up the fight to protect our children's health. It's worth it and it works. We've worked so hard here to warn our children about the dangers of drugs, to tell them drugs are illegal, drugs can kill them, drugs can ruin their lives. We've worked hard to protect funding for Safe and Drug-Free Schools so the community can help parents. We must not weaken in this fight to protect our children from the dangers of tobacco.

We also have a duty to protect our families from the consequences of **alcohol** abuse. In the last year alone, 2,200 young people between the ages of 15 and 20 died in **alcohol**-related car crashes. We've worked hard to keep our children away from **alcohol**. Just last month I issued a rule telling the states they could lose some of their federal highway funds if they did not make it illegal for anyone under 21 to drive with **alcohol** in their blood -- zero tolerance.

Now the American Liquor Industry has made a decision that will make this hard work even harder. For a half-century now liquor companies have agreed not to advertise their products on television and radio for the simple reason that it was the right thing to do. This week, however, the liquor industry announced it would break its ban and put liquor ads on the air, exposing our children to such ads before they know how to handle **alcohol** or are legally allowed to do so. That is simply irresponsible.

I commend the four major broadcast networks for saying

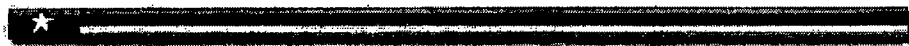
they continue to honor the ban and keep liquor ads off the air. I urge all other broadcasters to follow that example. Parents have a hard enough time raising good kids these days, and all of us have a responsibility to help them to make those jobs easier, not harder.

To tobacco companies we should all say, sell your products to adults, but draw the line on kids. And to liquor companies we should say, you were right for the last 50 years when you didn't advertise on television; you're wrong to change your policy now. This is no time to turn back. Get back on the ban. That's the best way to protect all our families.

Our goal must be to help parents pass on their values to their children, help our children act responsibly, and teach them to take charge of their own lives. If we do this, America's days -- best days are still ahead.

Thanks for listening.

End



To comment on this service: feedback@www.whitehouse.gov

Topic 5.3.8: Compromise Proposals
Posted by: Matthew Myers on 03-Sep-96 at 08:18 AM
Subject: Lott Compromise

There has been a great deal of coverage over a so-called compromise allegedly being brokered by Trent Lott. The reports say the compromise would enact into law the FDA Rule, but strip FDA of jurisdiction and wipe out all product liability suits.

Our position is: We will oppose any legislative compromise that

1. Weakens the FDA Rule,
2. Strips FDA or a comparable agency of the jurisdiction we have fought to get the government to assert,
3. Frees the industry from liability for past and future wrongdoing,
4. Fails to require the industry to make available all of its internal documents concerning nicotine, addiction, and health
5. Lacks an effective enforcement mechanism, or
6. Preempts stronger state and local action.

Now that Congress is returning, we urge everyone to contact their Member to urge support for FDA and opposition to any weakening proposals, even if they are promoted with all the glitz and gloss we can expect.

Please let us know of any rumors or information you obtain on this subject.

REMEMBER - CONGRESS IS IN SESSION FOR ONLY A MONTH - YOU NEED TO ACT NOW

- Comments By 3:00 PM E-mails

1 to American families, Senator Dole continues to lead misguided efforts to repeal it. This law
2 is good for families, it is good for America, and it would not be the law today without the
3 Democratic Party. Now we want to take the next step. We believe parents should be able to take
4 unpaid leave from work so they can do their job as parents: to do things like go to parent-teacher
5 conferences or take a child to the doctor. We support allowing employee-choice flex time so
6 employees can trade in earned overtime hours to spend more time with their families.

7 *Violence in entertainment.* President Clinton and Vice President Gore have led the fight
8 to help parents control what their children see on television. Because of their leadership,
9 Congress passed a law requiring all new televisions to include a device called a V-chip that will
10 block violent programs when it is activated by an adult. Senator Dole likes to talk about TV
11 violence, but when it came time to act, he stood with a small minority to oppose the bipartisan V-
12 chip bill. The President announced a breakthrough agreement with the media and entertainment
13 industries to develop a rating system for TV shows similar to the motion picture rating system,
14 so parents can make informed decisions about what they want their children to watch. When
15 parents control the remote, it's not censorship, it's personal responsibility for their children's
16 upbringing. We echo the President's call to the entertainment industry: Work harder to develop
17 and promote movies, music, and TV shows that are suitable -- and educational -- for children.

18 *Tobacco.* Cigarette smoking is rapidly becoming the single greatest threat to the health of
19 our children. We know that 3,000 young people start smoking every day, and 1,000 of them will
20 lead shorter lives because of it. Despite that, Senator Dole and other Republicans continue to
21 ignore volumes of medical research to make baffling claims that cigarettes are not addictive.
22 They even argue with distinguished Republican experts like President Reagan's Surgeon General
23 C. Everett Koop. President Clinton and Vice President Gore understand that we have a
24 responsibility to protect our children's future by cracking down on illegal sales of tobacco to
25 minors and by curbing sophisticated advertising campaigns designed to entice kids to start
26 smoking before they are old enough to make an informed decision. The President has proposed
27 measures to cut off children's access to cigarettes, crack down on those who sell tobacco to
28 minors illegally, and curtail advertising designed to appeal to children. We believe tobacco
29 companies should market to adults if they wish, but take the responsibility to draw the line on
30 children.

31 *Child support.* Nobody has the right to walk away from the responsibility to care for his
32 or her children. If you owe child support, paying it fully and promptly is just the first step in
33 living up to your responsibility as a parent. The Clinton Administration has made a determined
34 effort to crack down on deadbeat parents, collecting a record \$11 billion in 1995 through tough
35 enforcement -- almost a 40 percent increase over 1992. President Clinton issued an Executive
36 Order to track down federal workers who fail to pay child support, and force them to pay. The
37 Democratic Party believes that the toughest possible child support enforcement must be a central
38 part of any real welfare reform plan, including the President's plan to deny drivers licenses and
39 professional licenses to people who don't pay their child support. We must tell deadbeats: If you
40 neglect your responsibility to your children, we'll suspend your license, garnish your wages,

Mistake

5-9259
false statements about nicotine and danger to public health

tobacco company, line — ~~between and issue by attaching~~
FDA reform
attach FDA indirectly — FDA
reform

— milk comparison —

misrepresenting ^{proposed} FDA rule

conclusions, rhetoric down

1 page fact sheet

CAMPAIGN For TOBACCO-FREE Kids

NATIONAL CENTER FOR TOBACCO-FREE KIDS

For Immediate Release
September 6, 1996

Contact: Brian Ruberry
202 296-5469

Statement By
William D. Novelli, President
CAMPAIGN FOR TOBACCO-FREE KIDS
on
Sen. Joe Lieberman's Support for the FDA Rule

We applaud Sen. Lieberman's public support for the historic FDA rule announced by President Clinton last month. We anticipate he will take a leadership role in the Senate to ensure that marketing and sales of tobacco products to children are restricted as the FDA rule provides.

In his statement, Sen. Lieberman said, "From the beginning, I have completely and publicly supported President Clinton's courageous plan to combat tobacco marketing and sales to children."

We say thank you to Sen. Lieberman for his support and look forward to his support in the future, for the lives of America's children are at stake

2022965427

SEP-06-96 10:59 FROM: TOBACCO-FREE KIDS

ID: 2022965427

PAGE 3/3

facsimile
TRANSMITTAL

to: Bill Novelli/Kay Kahler
fax #: 296-5427
re: Tobacco
date: September 5, 1996
pages: 1, including this cover sheet

Here is a statement from Senator Joe Lieberman on the President's proposals regarding tobacco and children:

"From the beginning, I have completely and publicly supported President Clinton's courageous plan to combat tobacco marketing and sales to children."

If you have any questions, you can reach me at my home number, 202-583-5697.

From the desk of...

James E. Kennedy
Communications Director
Office of Senator Joe Lieberman
United States Senate
Washington, DC 20510

(202) 224-4041 (w), (202) 583-5697 (h)
Fax: (202) 224-4150

-6-5820-

418 What do you think - Jeren

Scheduling Advice Memorandum

FROM: ANNE WALLEY AND STEPHANIE STREETT

DATE: SEPT 9, 1996
No Ack needed

TO:

DOUG SOSNIK
EVELYN LIEBERMAN
RAHM EMANUEL
JOHN EMERSON
DON BAER
JACK GIBBONS
JOHN HILLEY
MARCIA HALE
MICHAEL MCCURRY
ALEXIS HERMAN
NANCY HERNREICH
HAROLD ICKES
ANDREW SENS
ANTHONY LAKE
BRUCE LINDSEY
AL SULLIVAN
KATIE MCGINTY

MACK MCLARTY
JACK QUINN
LEON PANETTA
TODD STERN
RON KLAIN
CAROL RASCO
LAURA TYSON
BOB NASH
PATTI SOLIS
GEORGE STEPHANOPOULOS
ANN STOCK
KITTY HIGGINS
MELANNE VERVEER
DANNY WEXLER
MAGGIE WILLIAMS
KIM TILLEY
JEREMY BEN-AMI

RE:

INVITES POTUS TO A NATIONAL CANCER INSTITUTE
SPONSORED CONFERENCE ON TOBACCO USE PREVENTION
"BUILDING MOMENTUM FOR TOBACCO PREVENTION - PLANNING
FOR THE FUTURE" OCT 22-23, 1996, ARLINGTON, VA.
The Scheduling Office has received the attached invitation.
Please advise us:

- ☐ The President does not need to accept.
☐ The President does not need to accept but should send a representative.

☐ If you think the President should accept, please submit a scheduling proposal
WITH THE INVITATION ATTACHED, ASAP.

Your Additional Comments:

PLEASE RETURN THIS MEMO TO PETE SELFRIDGE IN ROOM 184 BY SEPT 22, 1996



JOHN R. SEFFRIN, PH.D.
Chief Executive Officer

August 2, 1996

President William J. Clinton
1600 Pennsylvania Avenue, NW
Washington, DC 20500

Dear Mr. President:

The American Cancer Society, in collaboration with the National Cancer Institute, is sponsoring a conference entitled, "Building Momentum for Tobacco Prevention - Planning for the Future." More than 200 state and community leaders in the field of tobacco use prevention from 17 states will attend this conference. The conference is held under the auspices of the American Stop Smoking Intervention Study, a public-private partnership designed to reduce cancer. Clinicians, community leaders and health officials from the public and private sectors will meet to learn about new methods to prevent nicotine addiction among youth, and the importance of building effective and durable tobacco use prevention programs.

As President, you have shown great and courageous leadership in protecting our youth from tobacco. Your participation as a keynote speaker at our conference would add enormously to our efforts to improve the health of our Nation, and especially the health of our children. Secretary Shalala has provided our keynote address in the past two conferences, but your presence and support would demonstrate to all the participants the tremendous importance of their work.

The conference will be held in the Airport Hilton Hotel (near Washington National Airport) on October 22-23, 1996. Depending upon your schedule, your address could occur at 9:00am on October 22, or at noon on either day. If those times are not possible for you, we will gladly shape our agenda to fit your needs, if you are willing to speak.

As you know, with 3,000 children a day adopting a lifelong addiction, tobacco use remains the leading preventable cause of premature death and disability in our society. Our efforts must protect our children. We have enjoyed the support of Secretary Shalala and her designation of Dr. Phil Lee to coordinate a national tobacco prevention effort. We hope you can join us at the conference.

I respectfully extend this invitation on behalf of over 2 million volunteers, and we await your response.

Sincerely,

John R. Seffrin, PhD

JRS/rt/cs

Date Rec'd

8/7/96

*Ltr Asn'd

WJH

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File Smoking
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Office on Smoking and Health
National Center for Chronic Disease Prevention
and Health Promotion
Centers for Disease Control and Prevention
4770 Buford Highway, N.E. (MS-K50)
Atlanta, Georgia 30341-3724

Phone: (770)-488-5705
Press Line: (770)-488-5493
Fax: (770)-488-5939
Internet
Homepage: <http://www.cdc.gov/nccdphp/osh/tobacco>

To: **Elizabeth Drye**

Date: 10/8/96

Phone: 202-456-5573

Fax: 202-456-7028

Pages (including cover): 10

From: Llewelyn Grant

Message: If you require additional information, please don't hesitate to call me at 770-488-5493.



U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service



Office on Smoking and Health - Smoking and Health Information

Cigarette Smoking-Related Mortality

Cigarette smoking is the single most preventable cause of premature death in the United States.(1) About 418,000 Americans died from cigarette smoking in 1990. In fact, one in every five deaths in the United States is smoking-related.(1) Every year smoking kills more than 276,000 men and 142,000 women.(1)

- ▼ About 10 million people in the United States have died from causes attributed to smoking (including heart disease, emphysema, and other respiratory diseases) since the first Surgeon General's report on smoking and health in 1964--2 million of these deaths were the result of lung cancer alone.(2)
- ▼ Between 1960 and 1990, deaths from lung cancer among women have increased by more than 400 percent--exceeding breast cancer deaths in the mid-1980s.(3) The American Cancer Society estimated that in 1994, 59,000 women died of lung cancer and 46,000 died from breast cancer.(4)
- ▼ Men who smoke increase their risk of death from lung cancer by more than 22 times and from bronchitis and emphysema by nearly 10 times. Women who smoke increase their risk of dying from lung cancer by about 12 times and the risk of dying from bronchitis and emphysema by more than 10 times. Smoking triples the risk of dying from heart disease among middle-aged men and women.(1)
- ▼ Every year in the United States, premature deaths from smoking rob more than five million years from the potential lifespan of those who have died.(1)
- ▼ On average, smokers die nearly seven years earlier than nonsmokers.(2)
- ▼ Annually, exposure to secondhand smoke (or environmental tobacco smoke) causes an estimated 3,000 deaths from lung cancer among American adults.(5) Scientific studies also link secondhand smoke with heart disease.

References:

1. Centers for Disease Control and Prevention. Smoking-Attributable Mortality and Years of Potential Life Lost--United States, 1990. *Morbidity and Mortality Weekly Report* 1993; 42(33):645-648.
2. Centers for Disease Control and Prevention. Office on Smoking and Health, unpublished data, 1994.
3. Centers for Disease Control and Prevention. Mortality Trends for Selected Smoking-Related and Breast Cancer--United States, 1950-1990. *Morbidity and Mortality Weekly Report* 1993; 42(44):857, 863-866.
4. American Cancer Society. *Cancer Facts and Figures--1994*. Atlanta, Georgia; American Cancer Society, 1994.
5. U.S. Environmental Protection Agency. *Respiratory Health Effects of Passive Smoking: Lung Cancer and Other Disorders*. Washington, D.C.: U.S. Environmental Protection Agency, Office of Health and Environmental Assessment, Office of Research and Development, EPA/600/6-90/006F, December 1992.

Cigarette Smoking Deaths, 1990(1)

DISEASE	MEN	WOMEN	OVERALL
CANCERS:			
Lung	81,179	35,741	116,920
Lung from ETS	1,055	1,945	3,000
Other	21,659	9,743	31,402
TOTAL	103,893	47,429	151,322
CARDIOVASCULAR DISEASES:			
Hypertension	3,299	2,151	5,450
Heart Disease	88,644	45,591	134,235
Stroke	14,978	8,303	23,281
Other	11,682	5,172	16,854
TOTAL	118,603	61,117	179,820
RESPIRATORY DISEASES:			
Pneumonia	11,292	7,881	19,173
Bronchitis/ Emphysema	9,324	5,541	14,865
Chronic Airway Obstruction	30,385	18,579	48,982
Other	787	668	1,455
TOTAL	51,788	32,689	84,475
DISEASES AMONG INFANTS	1,006	705	1,711
BURN DEATHS	863	499	1,362
All CAUSES	276,153	142,537	418,690

3676

For more information about cigarette-related mortality contact your local chapters of the American Heart Association, American Lung Association, and the American Cancer Society.

Office on Smoking and Health
Centers for Disease Control and Prevention
1995



DISEASES CAUSED BY AND RELATED TO TOBACCO USE¹

Cigarette smoking is a cause of:

- Coronary heart disease
- Atherosclerotic peripheral vascular disease
- Cerebrovascular disease
- Cancers of the lung, larynx, mouth, esophagus, and bladder
- Chronic obstructive pulmonary disease
- Intrauterine growth retardation
- Low-birthweight babies

Cigarette smoking is a probable cause of:

- Unsuccessful pregnancy
- Increased infant mortality
- Peptic ulcer disease

Cigarette smoking is a contributing factor for:

- Cancers of the pancreas, kidney, and cervix

Cigarette smoking is associated with:

- Cancer of the stomach

Involuntary smoking (environmental tobacco smoke) is a cause of:

- Lung cancer in nonsmokers

Involuntary smoking (environmental tobacco smoke) increases:

- The frequency of respiratory infections and symptoms in the children of parents who smoke

Smokeless tobacco is a cause of:

- Oral cancer
- Oral leukoplakia

¹ All statements about causality are taken from various Reports of the Surgeon General and are summarized in the 1989 Report of the Surgeon General (pages 20-21), with the exception of the statements about bladder cancer, cervical cancer, oral leukoplakia. Tobacco smoking was reported to be a cause of bladder cancer and a contributing factor for cervical cancer in the 1990 Report of the Surgeon General. Smokeless tobacco was stated to be "responsible for the development of a portion of oral leukoplakias in both teenage and adult users" in the 1986 Report on Smokeless Tobacco.

Current Trends**Cigarette Smoking-Attributable Mortality
and Years of Potential Life Lost — United States, 1990**

Cigarette smoking is the single most preventable cause of premature death in the United States (1). An estimated 390,000 smoking-attributable deaths in the United States occurred in 1985 (1), and more than 434,000 deaths occurred in 1988 (2); in 1988, an estimated 1,198,887 years of potential life lost (YPLL) before age 65 were attributed to smoking (2). To estimate the national impact of cigarette smoking on mortality and YPLL, calculations were performed using the Smoking-Attributable Mortality, Morbidity, and Economic Cost (SAMMEC) software (3). This report summarizes the results of this analysis.

SAMMEC uses attributable risk formulas to estimate the number of deaths from neoplastic, cardiovascular, respiratory, and pediatric diseases associated with cigarette smoking (3). Estimates for adults (aged ≥ 35 years) and infants (aged < 1 year) were based on 1990 mortality data, the 1990 prevalence of cigarette smoking among adults, and 1989 data on smoking prevalence among pregnant women from CDC's National Center for Health Statistics (4,5; CDC, unpublished data, 1993). The number of burn deaths was obtained from the National Fire Protection Association (6), and estimates of lung cancer deaths from environmental tobacco smoke (ETS) among nonsmokers were obtained from an Environmental Protection Agency report (7). The YPLL to age 65 years and to life expectancy were calculated using standard methodology (3), and smoking-attributable mortality (SAM) and YPLL rates were age-adjusted to the 1980 U.S. population to allow more accurate comparisons with 1988 SAM and YPLL.

During 1990, 418,690 U.S. deaths (approximately 20% of all deaths) were attributed to smoking (Table 1). Overall, approximately twice as many deaths occurred among males as among females. A total of 179,820 of these deaths resulted from cardiovascular diseases; 151,322*, neoplasms; 84,475, respiratory diseases; and 1711, diseases among infants. Lung cancer (119,920 deaths*), ischemic heart disease (98,921 deaths), and chronic airway obstruction (48,982 deaths) accounted for the most deaths; combined, these conditions were responsible for 64.0% of all SAM.

Cigarette smoking resulted in 1,152,635 YPLL before age 65 years and 5,048,740 YPLL to life expectancy (Table 2). Compared with SAM and YPLL during 1988 (2), SAM declined by 3.6% and YPLL to age 65 years by 3.9% during 1990. SAM rates, total YPLL, and YPLL rates were higher for males than for females.

Reported by: Public Health Practice Program Office; Epidemiology Br, Office on Smoking and Health, National Center for Chronic Disease Prevention and Health Promotion, CDC.

Editorial Note: The slight decline in SAM during 1990 compared with 1988 primarily reflects the 10.4% decline in deaths from cardiovascular disease. The rate of these deaths in the United States has decreased substantially since 1968 (8). In contrast, deaths from lung cancer increased by 4.4% and deaths from chronic obstructive pulmonary disease by 4.8%. SAM from these two conditions continue to increase

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MMWR

August 27, 1993

Cigarette Smoking — Continued

TABLE 1. Relative risks* (RR) for death attributed to smoking and smoking-attributable mortality (SAM) for current and former smokers, by disease category and sex — United States, 1990

Disease category (ICD-9 code) [†]	Male			Female			Total SAM
	RR		SAM	RR		SAM	
	Current smokers	Former smokers		Current smokers	Former smokers		
<i>Adult diseases (persons aged ≥35 yrs)</i>							
<i>Neoplasms</i>							
Lip, oral cavity, pharynx (140-149)	27.5	8.8	5,033	5.6	2.9	1,442	6,475
Esophagus (150)	7.6	5.8	5,658	10.3	3.2	1,616	7,284
Pancreas (157)	2.1	1.1	2,557	2.3	1.3	3,447	6,114
Larynx (161)	10.5	5.2	2,379	17.8	11.9	611	2,990
Trachea, lung, bronchus (162)	22.4	9.4	81,179	11.9	4.7	35,741	116,920
Cervix uteri (180)	NA [‡]	NA	NA	2.1	1.9	1,294	1,294
Urinary bladder (188)	2.9	1.9	3,046	2.6	1.9	950	4,026
Kidney, other urinary (189)	3.0	2.0	2,866	1.4	1.2	353	3,219
<i>Cardiovascular diseases</i>							
Hypertension (401-404)	1.9	1.3	3,299	1.7	1.2	2,151	5,450
Ischemic heart disease (410-414)							
Persons aged 35-64 yrs	2.8	1.8	25,431	3.0	1.4	7,701	34,132
Persons aged ≥65 yrs	1.6	1.3	39,918	1.6	1.3	25,871	64,789
Other heart diseases (390-398, 415-417, 420-429)	1.9	1.3	23,295	1.7	1.2	12,019	35,314
<i>Cerebrovascular diseases (430-438)</i>							
Persons aged 35-64 yrs	3.7	1.4	4,557	4.8	1.4	4,114	8,671
Persons aged ≥65 yrs	1.9	1.3	10,421	1.5	1.0	4,189	14,610
Atherosclerosis (440)	4.1	2.3	3,737	3.0	1.3	2,675	6,412
Aortic aneurysm (441)	4.1	2.3	5,913	3.0	1.3	1,382	7,295
Other arterial disease (442-449)	4.1	2.3	2,032	3.0	1.3	1,115	3,147
<i>Respiratory diseases</i>							
Pneumonia and influenza (480-487)	2.0	1.6	11,292	2.2	1.4	7,881	19,173
Bronchitis, emphysema (491-492)	9.7	8.8	9,324	10.5	7.0	5,541	14,865
Chronic airway obstruction (496)	9.7	8.8	30,385	10.5	7.0	18,597	48,982
Other respiratory diseases (010-012, 493)	2.0	1.6	787	2.2	1.4	668	1,455
<i>Pediatric diseases (persons aged <1 yr)</i>							
Short gestation, low birth weight (765)	1.8		285	1.8		222	507
Respiratory distress syndrome (769)	1.8		219	1.8		141	360
Other respiratory conditions of newborn (770)	1.8		214	1.8		160	374
Sudden infant death syndrome (792)	1.5		299	1.5		182	470
Burn deaths [§]			863			499	1,362
<i>Environmental tobacco smoke deaths**</i>							
			1,055			1,945	3,000
Total			276,153			142,537	418,690

*Relative to never smokers.

TABLE 2. Estimated number and age-adjusted rates* of smoking-attributable mortality (SAM) and smoking-attributable years of potential life lost (YPLL), by sex and age† — United States, 1990[‡]

Category	SAM		Smoking-attributable YPLL before age 65 yrs		Smoking-attributable YPLL to life expectancy	
	Estimated no.	Rate	Estimated no.	Rate	Estimated no.	Rate
Men	275,147	527.8	732,389	1,919.1	3,124,208	6,233.7
Women	141,832	224.8	308,801	764.6	1,797,024	3,070.7
Infants	1,711	NA [§]	111,445	NA	127,508	NA
Total	418,690	364.5	1,152,635	1,325.8	5,048,740	4,541.3

* Per 100,000 persons aged ≥35 years, adjusted to the 1980 U.S. population.

† Men and women=aged ≥35 years; infants=aged <1 year.

‡ SAM rates and YPLL estimates and rates do not include 3000 deaths from passive smoking because such data were not available.

§ Not available.

Cigarette Smoking — Continued

because of the long latency period between the onset of smoking and the development of disease.

The higher SAM and larger number of YPLL among males is consistent with previous reports (1,2). Men in the United States are more likely to smoke and to smoke more cigarettes per day than women (1,4). However, the smoking prevalence among men has declined substantially since 1965 (1). The smoking prevalence among women, after increasing in the 1960s, also has declined since the late 1970s (1). Therefore, future estimates of SAM and YPLL will most likely indicate a smaller difference between men and women.

The SAM and YPLL described in this report may be underestimated for at least four reasons. First, these estimates are based on current smoking prevalence data, whereas most smoking-attributable deaths during 1990 resulted from the higher smoking prevalence during earlier decades (2). Second, the SAM estimate for infants may be substantially underestimated because previous research suggests that approximately 10% of the 38,351 infant deaths that occurred during 1990 may be attributable to smoking (1,9). Third, the SAM estimates do not include deaths from other conditions, such as leukemia (2) and peptic ulcer disease (1), that also may be associated with smoking. Finally, these estimates do not include mortality caused by cigar smoking, pipe smoking, or smokeless tobacco use. The SAM and YPLL estimates in this report are not adjusted for confounders (e.g., alcohol), which may lower the estimates for laryngeal and certain upper gastrointestinal cancers (1).

The decrease in the prevalence of cigarette smoking since the 1960s has contributed to the decline in SAM (1,4). Maintaining this decline will require continued reduction in the prevalence of smoking. The human and economic costs associated with smoking require continued vigorous efforts to prevent the initiation of smoking, to encourage smoking cessation, and to protect nonsmokers from the adverse effects of ETS. Because many factors influence both smoking initiation and smoking cessation, multiple approaches are necessary (1) including 1) school-based health education; 2) reducing minors' access to tobacco products; 3) more extensive counseling by health-care providers about smoking cessation; 4) developing and enacting strong, clean indoor air policies and laws; 5) restricting or eliminating advertising targeted toward persons aged <18 years (10); and 6) increasing tobacco excise taxes.

References

1. CDC. Reducing the health consequences of smoking: 25 years of progress—a report of the Surgeon General, 1989. Rockville, Maryland: US Department of Health and Human Services, Public Health Service, 1989; DHHS publication no. (CDC)89-8411.
2. CDC. Smoking-attributable mortality and years of potential life lost—United States, 1988. *MMWR* 1991;40:62-3,69-71.
3. Shultz JM, Novotny TE, Rice DP. Smoking-Attributable Mortality, Morbidity, and Economic Cost (SAMMEC) version 2.1 [Software and documentation]. Atlanta: US Department of Health and Human Services, Public Health Service, CDC, 1992.
4. CDC. Cigarette smoking among adults—United States, 1990. *MMWR* 1992;41:354-5,361-2.
5. CDC. Pregnancy risks determined from birth certificate data—United States, 1989. *MMWR* 1992;41:556-63.
6. Miller AL. The U.S. smoking-material fire problem through 1990: the role of lighted tobacco products in fire. Quincy, Massachusetts: National Fire Protection Association, 1993.
7. US Environmental Protection Agency. Respiratory health effects of passive smoking: lung cancer and other disorders. Washington, DC: US Environmental Protection Agency, Office of Health and Environmental Assessment, Office of Atmospheric and Indoor Air Programs, 1992.

Cigarette Smoking — Continued

8. American Heart Association. 1993 Heart and stroke facts statistics. Dallas: American Heart Association, 1992.
9. NCHS. Advance report of final mortality statistics, 1990. Hyattsville, Maryland: US Department of Health and Human Services, Public Health Service, CDC, 1993. (Monthly vital statistics report; vol 41, no. 7, suppl).
10. Public Health Service. Healthy people 2000: national health promotion and disease prevention objectives—full report, with commentary. Washington, DC: US Department of Health and Human Services, Public Health Service, 1991; DHHS publication no. (PHS)91-50212.

Notice to Readers**Announcement of Eighth National Conference
on Chronic Disease Prevention and Control**

CDC, the Association of State and Territorial Health Officials, and the Association of State and Territorial Chronic Disease Program Directors will cosponsor the Eighth National Conference on Chronic Disease Prevention and Control, "The Role of Chronic Disease Prevention and Control in a Changing Health Environment." The conference will be November 17-19, 1993, in Kansas City, Missouri, and is open to the public.

The conference will emphasize interactions among federal, state, and local health departments; voluntary health agencies; and professional organizations. Topics will include worksite health promotion, nutrition and health, chronic disease and young persons, diabetes epidemiology, cancer epidemiology, older adults and their health, cardiovascular disease epidemiology, tobacco and health, use of local data for decision making, building community partnerships for healthy behavioral change in schools, and pitfalls of community intervention.

Additional information is available from CDC's National Center for Chronic Disease Prevention and Health Promotion, Mailstop K-43, 4770 Buford Highway, NE, Atlanta, GA 30341-3724; telephone (404) 488-5390; fax (404) 488-5962.

Erratum: Vol. 42, No. SS-3

In the *CDC Surveillance Summaries* report, "Surveillance for Gonorrhea and Primary and Secondary Syphilis Among Adolescents—United States, 1981-1991," the last column of Table 2 (page 4) contained an error. In the column "Total Population, Female," the rate for the South should be 1479.4.

E X E C U T I V E O F F I C E O F T H E P R E S I D E N T

16-Dec-1996 07:32pm

TO: (See Below)

FROM: Barry J. Toiv

SUBJECT: tobacco

Message Creation Date was at 16-DEC-1996 15:56:00

Michael Frisby (Wall St. Journal) is working on a piece for Friday's paper on tobacco. Business Week has a piece this week entitled "Is Big Tobacco Ready to Deal" that features the RJR CEO suggesting that they might have some interest in the old Philip Morris proposal. Apparently, they're telling Frisby they'd like to deal.

They are also saying that RJR (or other industry folks) have spoken with Leon about this. He's not gotten any indication that the W.H. has expressed interest and he doesn't understand politically why we would. But industry, as we know, has been throwing Leon's name around as a way of suggesting something might happen.

Frisby wants to get a sense of what's going on, what happens next, what the W.H. perspective is, and what we might eventually do. Since Leon has handled this, he wants to talk to Leon, and he wants to talk to Erskine -- in part to find out whether there will be any differences in how we handle the issue when Erskine takes over, given his background, etc.

So, the question is, do we ask Leon and/or Erskine to make themselves available to Frisby, or do we handle this some other way? I assume our message is unchanged -- legislation is preferable but it has to accomplish the goals of the regulations, and we're open to suggestions of alternatives to FDA. But the question is whether something real is happening here. It's been my understanding that nothing real is happening, but who knows?

It's a little unclear to me who's handling this now, with Jen O'Connor gone. Does anybody have any idea?

Distribution:

TO: MCHUGH_L
TO: DRYE_E
TO: Michael D. McCurry
TO: Douglas B. Sosnik
TO: Victoria Radd
TO: Katherine K. Wallman

CC: PALMIERI_J

6-6210

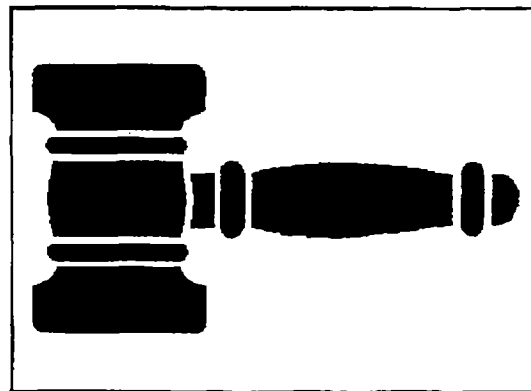
U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
OFFICE OF THE GENERAL COUNSEL

PHONE: (202) 690-6318

FAX: (202) 690-7998

DATE: December 16, 1996

TO: **ELIZABETH DRYE**
456-7028



FROM: **ANDREW D. HYMAN**
Special Assistant to the General Counsel
U.S. Department of Health and Human Services
Office of the General Counsel, Room 707F
200 Independence Ave., SW
Washington, D.C. 20201

COMMENTS: Attached is the article we discussed. I'll get you info about this week's MMWR this afternoon.

No. of Pages (including cover): 5

Lawmakers slow to fight for tobacco
Despite rhetoric, no bills pending

Raleigh News & Observer

Monday, December 16, 1996

By JAMES ROSEN, Washington Correspondent

WASHINGTON -- When President Clinton announced plans last year for the Food and Drug Administration to regulate nicotine as a drug, alarmed cigarette makers sought help from Congress and angry tobacco-state lawmakers vowed to block the move with legislation.

More recently -- just last week, in fact -- Sens. Lauch Faircloth and Jesse Helms promised a North Carolina farmers' convention in Winston-Salem that they would join Kentucky's two senators to lead a campaign in Washington on behalf of tobacco.

But in the 16 months since Clinton and Dr. David A. Kessler, his soon-to-depart head of the Food and Drug Administration, unveiled their drive against youth smoking, neither Helms, Faircloth nor any other lawmaker has introduced a single piece of legislation to counter the program.

And despite their continuing protests against FDA control of tobacco, there are no signs of legislative action any time soon. Helms, Faircloth and Sens. Wendell Ford and Mitch McConnell of Kentucky met in Helms' office two weeks ago, but no concrete plan emerged from the session -- at least, none that they're willing to acknowledge.

"We have got no specific legislation in mind," Helms said after the meeting.

An aide to Faircloth acknowledged that, despite the senator's fiery words at the annual convention of the N.C. Farm Bureau about launching a tobacco campaign, there was really nothing in the works.

"This was a tobacco crowd," said Peter Hans, Faircloth's spokesman. "They were wanting red meat, and he gave it to them. It was a bunch of political rhetoric. In terms of what's happening, there's nothing happening."

Helms, who just won re-election, and Faircloth, whose term ends in 1998, aren't the only politicians moving with glacial speed to protect tobacco.

In the House of Representatives, Rep. Thomas Bliley of Virginia -- home to the No. 1 cigarette maker, Philip Morris Cos. Inc. -- has no plans to take up tobacco on the House Commerce Committee, the powerful panel he heads.

In a speech last week, Bliley outlined his committee's agenda for the new session of Congress. He did not mention tobacco.

"That matter is in the courts," Bliley said of the new FDA regulations. "I expect the courts will resolve it, not the Congress."

The tobacco companies say they support the FDA program's goal of reducing youth smoking by clamping down on the advertising and sale of cigarettes to young people. But the companies fiercely

oppose classifying tobacco as a drug and putting the FDA in charge of regulating it -- moves they fear could lead to tighter controls or even the prohibition of smoking.

Relying on the courts

The tobacco industry is no longer looking to Washington for help. Its hopes lie in a federal court in Greensboro, where the country's largest cigarette makers, advertising agencies and other firms have sued the government over the FDA regulations.

"Our strategic decision-makers have concluded that court is the best place to address the FDA proposals," said Thomas Lauria, a spokesman for the Tobacco Institute, the main industry lobby in Washington.

The plaintiffs want Judge William Osteen to issue an injunction blocking the rules, and the two sides will present oral arguments on Feb. 10. The regulations' first provision is to take effect Feb. 28, with the start of a national ban on tobacco sales to people under 18 and a requirement that vendors ask for proof of age.

Other measures would be phased in over the next 18 months:

Restrictions on tobacco advertisements in youth publications and on billboards near schools or playgrounds;

Limits on where cigarette vending machines can be placed, and where cigarettes can be displayed in stores;

Elimination of tobacco brand-name sponsorship of concerts or sporting events;

An end to promotional giveaways of cigarettes or T-shirts, gym bags and other items with their names or logos.

The legal challenge is one explanation Helms and other tobacco-state lawmakers give for their failure to advance legislation on the FDA regulations.

They say they want to see how the judge rules on the tobacco companies' claim that the FDA lacks legal authority to regulate their product -- even though the initial decision in February, whatever it is, will be appealed to a higher court, and the legal battle could drag on for years.

Hope for compromise

There are other reasons for the politicians' reluctance. Kessler's recent announcement that he will resign as FDA administrator has raised hopes in tobacco circles that Clinton will replace him with a less vehement foe of smoking.

With Clinton and Republican congressional leaders promising greater cooperation, a more moderate FDA chief might enforce the youth-smoking regulations less vigorously -- and be more open to a legislative compromise.

In one widely circulated compromise scenario, the tobacco companies would accept nearly all of the regulations themselves in exchange for transferring administration of the rules away from the FDA to another government agency -- a change that would avoid tobacco being classified as a drug.

While some anti-smoking groups reject moving the regulations beyond FDA control, administration officials appear open to the idea.

"The administration has always been willing to consider legislation to implement the rules, and the administration has been willing to look at the issue of who administers the rules," said Barry Toiv, a White House spokesman.

Beyond the FDA controversy, there have been recent reports of a possible "global settlement" that would end various states' lawsuits against the tobacco companies -- most of them seeking to recover what it has cost the states to treat smoking-related illnesses -- as well as several Justice Department probes of the cigarette makers.

Steven Goldstone, the head of RJR Tobacco's parent company -- RJR Nabisco Holdings Co. -- recently said he might accept such a settlement. A resolution of the FDA rules dispute could be part of the deal.

Rift in the family

Another obstacle to legislative movement on the FDA rules is the big cigarette manufacturers' competitive mistrust of one another.

Despite the companies' attempt to present a unified front, congressional aides and tobacco insiders from North Carolina say the relationship between Philip Morris and R.J. Reynolds was badly strained this year. RJR executives were furious in May when Philip Morris -- without consulting with or even notifying the other tobacco companies -- launched a glossy campaign aimed at gaining a congressional compromise on the FDA rules. The campaign went nowhere.

"We were not aware until the morning of the announcement that they were going to do that," said Peggy Carter, an RJR spokeswoman. "It's sort of like with your family members -- how your own brothers can tick you off, and you get very mad for a couple days and then it blows over."

Although the two companies' relations reportedly have been repaired, there are residual hard feelings. Congressional aides say their bosses have told the industry it must be completely unified before any legislation can move.

"We have a hard enough time passing tobacco legislation even when we're all in agreement," said Mark Eaton, a former Helms aide who is now managing director of the Burley and Dark Leaf Trade Association, the burley growers' lobby in Washington. "When the tobacco family is not in agreement, then we've got a hell of a hard time."

There are even conflicts among the tobacco-state lawmakers. Helms told the North Carolina farmers last week that Kessler decided to resign after Bliley, the Virginia congressman who heads the commerce panel, warned him that he would make Kessler's life miserable. Bliley denied Helms' account, according to the Greensboro News & Record.

No constituency

But the most basic explanation for legislative malaise on the FDA regulations could be simple political realism. Tobacco-state

lawmakers may have decided that there just aren't enough votes in Congress to pass legislation that helps cigarette makers.

"It's very dangerous for us to take a tobacco bill to the floor," Eaton said. "There are guys lining up to put amendments on it that are detrimental to the industry."

The handwriting has been on the wall this year. An attempt in the House to end the federal tobacco-support program failed by just two votes, the smallest margin ever. Bob Dole, the GOP presidential candidate, was widely rebuked for suggesting that tobacco might not be addictive, and for taking political contributions from cigarette makers.

The FDA drive against youth smoking, meanwhile, was a big hit in opinion polls, and Clinton campaigned on it.

"Nobody wants to explain to voters in the next election campaign why they cozied up to tobacco interests," said CNN political analyst Bill Schneider. "Outside of growers in North Carolina and a few other states, there is no constituency for tobacco in this country."

"Most smokers are trying to stop. They approve of treating tobacco as a drug."

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THE WHITE HOUSE
WASHINGTON

December 16, 1996

Mr. David P. Nicoli, Vice President
Federal Government Affairs-Tobacco
Philip Morris Companies, Inc.
1341 G Street, NW, Suite 900
Washington, DC 20005

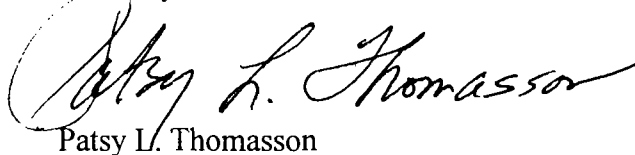
Dear David:

Thank you very much for sending me the information on the plan that was announced by Philip Morris and United States Tobacco.

I will take the opportunity to read it and I will forward it to the Domestic Policy Council.

Too, I was serious about providing names for potential candidates for the Food and Drug Administration. We hope you will submit names to us.

Sincerely,

A handwritten signature in black ink, reading "Patsy L. Thomasson". The signature is fluid and cursive, with a large initial "P" and "T".

Patsy L. Thomasson
Deputy Assistant to the President and
Deputy Director of Presidential Personnel

cc: Chris Jennings; DPC

PHILIP MORRIS

DEC 12 1996

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December 12, 1996

Ms. Patsy L. Thomasson
Deputy Assistant to the President
and Deputy Director for Presidential Personnel
The White House
Washington, DC 20500

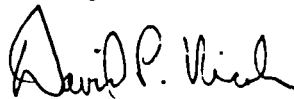
Dear Patsy:

It was a pleasure getting to speak with you last night. It is apparent that you have a great job, and a challenging one as you move to staff up the Administration for its second term.

Per our discussion, I have enclosed a description of the plan that Philip Morris and United States Tobacco unveiled last May along with clips from the Wall Street Journal laying out the President's reaction to that proposal. I hope you have time to review it and I would be happy to address any questions or comments that you or anyone else at the White House has in these areas.

Again, it was a real pleasure meeting you last night. I hope we have a chance to speak again soon.

Sincerely,



David P. Nicoli

Enclosure